

AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows:

Example 4. The effect of pharmaceutical compositions and methods of use.

A symptomatic patient with severe form of asthma. Her breathlessness was not controlled even though she was on a maximal medical therapy for asthma was given Mycobacterium w containing pharmaceutical composition (as provided in Example 1A of this invention) at a dosage of 0.2 ml per week administered intradermally initially followed by a dosage of 0.1 ml per week administered intradermally; both dosages were administered at the interval of one per week. By four weeks patient became asymptomatic and number of drugs were gradually discontinued. Patient remained asymptomatic in spite of that.

Thus Mycobacterium w is found to be useful in management of asthma in making patient asymptomatic when maximal medical therapy fails to achieve this.

It is also useful in reducing the number of medicines a patient is taking.

Example 5. The effect of pharmaceutical compositions and methods of use.

A group of patients who were getting exacerbation of disease periodically were given Mycobacterium w containing pharmaceutical composition (as provided in Example 1A of this invention) at a dosage of 0.1 ml administered intradermally; the dosage was administered at the interval of one per fortnight. It was observed that none of them had exacerbation of disease.

Thus Mycobacterium w is found to be useful in eliminating/delaying exacerbation of the disease.

Example 6. The effect of pharmaceutical compositions and methods of use.

Several patients diagnosed to have bronchial asthma were given conventional therapy in the form of bronchodilators and steroids. This resulted in improvement in lung function as determined by spirometry in terms of FEV₁ and PEFR. The improvement with therapy was in the range of 15 to 20% from baseline, over a three month period of observation and it did not improve further. At the

end of three months patients were administered Mycobacterium w containing pharmaceutical compositions (as provided in Example 1A of this invention). It was administered as a dosage of 0.1 ml-through-nebuliser; the dosage was administered at the interval of one per week. Though these compositions are not known to have anti-inflammatory or broncho-dilator activity their administration resulted in further improvement in lung function as determined by FEV₁ and PEFR values. This improvement was in the range of 15 to 20% over and above the maximum values already achieved by conventional therapy.

The improvement in lung function was associated with subjective feeling of well being and improvement in quality of life. It also improved their performance scale. It also resulted in improvement in amount of physical exertion they can do without getting breathless.

Thus Mycobacterium w is useful in improving lung function , quality of life and performance.

Example 7. The effect of pharmaceutical compositions and methods of use.

In a group of patients having obstructive lung disease (chronic obstructive pulmonary disease, chronic bronchitis) and who were controlled by conventional therapy were observed for a period of three months and then a dosage of 0.1 ml of Mycobacterium w containing compositions (as provided in Example 1A and 1D of this invention) were added to the therapy and observed for another three months. The dosage was administered either through intra-dermal or inhalation route at a frequency of one dosage every fortnight. Average requirement of antibiotics used to treat infections and associated exacerbation of disease in the initial three months was 3.71. In the next three months when Mycobacterium w was coadministered the requirement came down to 2 from 3.71. None of them needed any antibiotic in last month of combined therapy.

Thus Mycobacterium w is useful in reducing requirement of antibiotics.

Example 8. The effect of pharmaceutical compositions and methods of use.

In a group of patients having obstructive lung disease (bronchial asthma, chronic bronchitis) and who were controlled by conventional therapy but still requiring hospitalization from time to time for management of acute exacerbations were observed for a period of three months and then a dosage

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of 0.1 ml of Mycobacterium w containing compositions (as provided in Example 1A and 1D of this invention) were added to the therapy and observed for another three months. The dosage was administered intradermally every fortnight for three months. The number of exacerbations were found to be three per person in first part of the study. In the second part it came down to one per person.